

REMARKS

This Amendment, filed in reply to the Office Action dated October 14, 2009, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-3, 5-16, 29 and 35 are rejected. Claims 1 and 35 are amended herewith. Claim 1 is amended to incorporate the subject matter of Claims 3 and 5 therein. Claim 35 is amended to be in independent form. Claims 2-5 are canceled herewith without prejudice or disclaimer.

No new matter is added by way of this Amendment. Entry and consideration of this Amendment are respectfully requested.

Claim to Priority

Applicants thank the Examiner for acknowledging Applicants' claim to foreign priority and for acknowledging receipt of a certified copy of Applicants' foreign priority document, namely JP 2004-174577.

Information Disclosure Statements

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed April 3, 2006.

Drawings

Applicants respectfully request that the Examiner acknowledge acceptance of the drawings filed on April 3, 2006.

Claims 1 and 2 are Enabled Under 35 U.S.C. § 112, First Paragraph

1. On page 2 of the Office Action, the Examiner rejects Claim 1 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In making the rejection, the Examiner contends that the specification is not enabling for the prevention of neurodegenerative diseases.

Without acquiescing to the merits of the rejection, Applicants note that Claim 1 as amended does not recite a method for “preventing” neurodegenerative diseases; thus, this rejection is moot.

Withdrawal of the rejection is respectfully requested.

2. On page 6 of the Office Action, the Examiner rejects Claims 1, 2 and 4 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. In making the rejection, the Examiner acknowledges that the specification is enabling for the treatment of cerebral infarction; however, the Examiner contends that the specification is not enabling for the treatment of all neurodegenerative diseases.

Solely to compact prosecution, and without acquiescing to the merits of the rejection, Applicants herewith amend Claim 1 to recite a method for treating cerebral infarction, to be commensurate with the subject matter acknowledged by the Office as being enabled. Moreover, Claim 4 is canceled herewith without prejudice or disclaimer, mooting the rejection of this claim. Applicants respectfully submit that the amendments overcome the rejection.

Withdrawal of the rejection is respectfully requested.

Claims 1, 2, 6, 7, 9-16, 29 and 35 are Patentable Under 35 U.S.C. § 102

On page 11 of the Office Action, the Examiner rejects Claims 1-3, 5-7, 9-16, 29 and 35 under 35 U.S.C. § 102(b) as allegedly being anticipated by Tateishi *et al.* (*Journal of Cerebral Blood Flow & Metabolism*, 2002, 22(6):723-734).

In making the rejection, the Examiner contends that Tateishi *et al.* discloses the intravenous administration of (2R)-2-propyloctanoic acid to rats, following induction of permanent middle cerebral artery inclusion (pMCAO). The Examiner further contends that Tateishi *et al.* discloses the intravenous administration of (2R)-2-propyloctanoic acid at a dose of 10mg/kg per day, which is alleged to significantly reduce infarct volume at 168 hours.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, and without agreeing with the basis of the rejection, Applicants note that Claim 1 is amended herewith to recite that “between about 100 mg to about 2,000 mg of (2R)-2-propyloctanoic acid or a salt thereof” is administered to the mammal. Applicants respectfully submit that Tateishi *et al.* does not disclose administration of (2R)-2-propyloctanoic acid or a salt thereof in an amount between about 100 mg to about 2,000 mg, either expressly or inherently, and thus does not anticipate the presently claimed invention.

Specifically, in contrast to the instant specification, which *inter alia* exemplifies the administration of (2R)-2-propyloctanoic acid at a dose of 4 mg/kg/hour and 8 mg/kg/hour for one hour (effecting administration of 100 mg or more of (2R)-2-propyloctanoic acid per administration to patients weighing 25 kg or more), Tateishi *et al.* employs a rat pMCAO model, in which rats are administered (2R)-2-propyloctanoic acid at a dose of only 10 mg/kg (which equates to only 0.4 mg/kg/hour). Accordingly, Tateishi *et al.* does not disclose each and every

element of the presently claimed invention, and thus cannot anticipate the presently claimed invention. Moreover, nothing in Tateishi *et al.*, nor the art as a whole, would have prompted those of ordinary skill in the art to administer such a high dose of (2R)-2-propyloctanoic acid, between about 100mg to 2000mg, as presently claimed, to cerebral infarction patients.

Withdrawal of the rejection is respectfully requested.

Claim 8 is Patentable Under 35 U.S.C. § 103

On page 12 of the Office Action, the Examiner rejects Claim 8 under 35 U.S.C. § 103(a) as allegedly being obvious over Tateishi *et al.* (*Journal of Cerebral Blood Flow & Metabolism*, 2002, 22(6):723-734) in view of Shirasaki *et al.* (U.S. Patent No. 5,837,706).

Tateishi *et al.* is relied upon in the rejection for the same reasons as discussed above in the anticipation rejection of Claims 1-3, 5-7, 9-16, 29 and 35. However, the Examiner acknowledges that Tateishi *et al.* does not disclose continuous intravenous administration of (2R)-2-propyloctanoic acid from an infusion bag. In an attempt to rectify such deficiency, the Examiner contends that, in view of Shirasaki *et al.*, those of ordinary skill in the art would readily have administered (2R)-2-propyloctanoic acid via intravenous drip infusion, citing column 4, lines 44-47, and column 5, lines 7-9, of Shirasaki *et al.* as support.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Initially, Applicants note that Shirasaki *et al.* is relied upon merely to disclose infusion bag administration, and neither discloses or suggests administering between about 100mg to about 2000mg of (2R)-2-propyloctanoic acid or a salt thereof to a patient. Accordingly, this

rejection is deficient for the same reasons presented above in response to the anticipation rejection over Tateishi *et al.*

Withdrawal of the rejection is respectfully requested.

Conclusion

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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